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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: American Forest & Paper Association Comments on Proposed Regulations for Prior Notice of Imported Food FDA Docket No. 02N-0278

Dear Sir or Madam:

These comments are submitted by the American Forest & Paper Association (AF&PA), the national trade association of the forest, pulp, paper, paperboard, and wood products industry. AF&PA represents member companies engaged in growing, harvesting, and processing wood and wood fiber, manufacturing pulp, paper, and paperboard products from both virgin and recycled fiber, and producing engineered and traditional wood products. AF&PA's members include manufacturers of over eighty percent of the paper, wood, and forest products produced in the United States. Because virtually all of the packaging and packaging component facilities of the member companies as well as all of their suppliers would be required to register under the proposed regulation, AF&PA is submitting these comments to ensure that the Food and Drug Administration (FDA) considers the full impact of its proposed regulations on the industry.

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The regulations as drafted will impose a very large burden on AF&PA member companies, with only a very limited and theoretical increase, if any, in the safety of the food supply. In proposing that the import notification requirements apply to packaging materials and other articles not in contact with food at the time of import, FDA has not followed Congress' express intent, and has created an unreasonable and unjustified burden on the industry and its suppliers. The preamble to the proposed regulations provides no food safety justification for the unnecessarily expansive approach. FDA has the clear congressional mandate and authority to define "article of food" for purposes of the import notification to exclude packaging materials and other articles that are not in contact with food at the time of import, and should do so. This would comport with the definition of "food for consumption" used in section 305 of the Bioterrorism Act, which requires registration of facilities that manufacture, process, pack, or hold "food for consumption." It is clear from the statutory language and the legislative history of both provisions that Congress intended to exclude packaging materials from both provisions. FDA should define "article of food" for purposes of the prior notice requirement to exclude packaging, food contact materials, and their components, consistent with the authorizing legislation, the explicit congressional intent, and FDA's mission to ensure the safety of the United States food supply.

I. FDA's Proposed Inclusion of Food Packaging and Other Food Contact Substances in the Definition of "Article of Food" is Not Consistent with Congressional Intent

Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires prior notification for imported "articles of food." For purposes of its proposed regulations, FDA has used a very broad definition of "article of food." In direct opposition to explicit legislative history FDA has proposed to define "article of food" to

encompass all "food" within its statutory jurisdiction under 201(f) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). In the preamble, FDA provides examples of products that are technically considered "food" under the FD&C Act, including "substances that migrate into food from food packaging and other articles that contact food." 68 Fed. Reg. 5428, 5430 (February 3, 2003).

During the enactment of the Bioterrorism Act, the packaging industry informed Congress that the definition of "food" broadly covers packaging and other food contact materials. If the Bioterrorism Act were to apply to the full range of articles that technically fall within the definition of "food" under the FD&C Act, all the requirements of the Bioterrorism Act, including the prior notice requirement for imports, would apply to manufacturers of packaging and packaging ingredients as well as thousands of other food contact articles. This realization came late in the legislative process. The congressional response was to insert clarifying language into the legislative history to provide explicit congressional intent on the proper scope of the Bioterrorism Act. Specifically, the Conference Report includes the following language:

> The Managers intend that the requirements of this section [307] should not be construed to apply to packaging materials if, at the time of importation, such materials will not be used for, or in contact with, food as defined under section 201 of the [FD&C Act].

H. R. Rept. No. 107-481, 107th Cong., 2d Sess. 137 (May 21, 2002). When the packaging industry explained that even this language might not be enough to evidence the clear intent of Congress to exclude packaging materials from the prior notification provisions, Congressman Shimkus, one of the Managers of the Bioterrorism Act, made this statement on the House floor:

> Mr. Speaker, in addition to my statement for the record on May 22, 2002 during floor consideration of H.R. 3448 [clarifying other sections of the Bioterrorism Act], let me clarify that language included in the Conference Report regarding Section 307 as it relates to food packaging materials. Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food.

148 Cong. Rec. E916, (daily ed. May 24, 2002). It is thus clear that Congress intended to limit the scope of "article of food" for purposes of the prior notice requirement to exclude packaging materials, unless such materials are used in direct contact with food at the time of import. As those packaging materials would be covered by the notice for the packaged food itself, there is no benefit to FDA's intended application of the prior notice requirement to other packaging materials.

As the agency authorized to implement the provisions of the Bioterrorism Act, FDA has discretion in interpreting the terms in that legislation. FDA is bound, however, by the language

of the statute and clear expressions of congressional intent. When Congress has spoken directly to an issue, the agency (and any reviewing court) must give effect to the unambiguously expressed intent of Congress. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984); *Food and Drug Administration v. Brown & Williamson Tobacco Corporation*, 529 U.S. 120, 126 (2000). For purposes of the prior notice of imports requirements, FDA was directed to develop regulations regarding the import or attempts to import "articles of food." Congress provided specific and unambiguous direction, however, that the interpretation of this term for purposes of the prior notice requirement is not to include food packaging unless such material is used in food at the time of import. This is consistent with the term "food for consumption" FDA used in section 305 of the Act. Due to the imperative to enact the Bioterrorism Act as quickly as possible to enable the necessary protections the Act affords, it is likely that small differences in language such as this occurred, but were not intended to have any import. In fact, Congress attempted to clarify, and to some degree reconcile, the provisions with the explanation that the prior notice requirements were not to apply to packaging and other food contact materials not in contact with food at the time of import. There is no other legislative history indicating that packaging and other food contact articles that are not in contact with food when imported are subject to prior notification. FDA has chosen to apply an expansive definition of "food" requiring prior notice in its proposed regulations implementing this requirement, in direct contravention to express congressional intent.

In the preamble to the proposed rule, FDA cites section 801(m) of the FD&C Act, as added by the Bioterrorism Act, as support for its requirement of a notification for "each article of food" in a shipment. The phrase "each article of food" appears nowhere in section 801(m). That section

does provide that the Secretary shall by regulation require the submission "of a notice providing the identity of each of the following: The article; the manufacturer and shipper of the article; . . ." Unlike the legislative history, however, it affords no explanation of what the "article" encompasses.

II. Inclusion of Food Packaging and Other Food Contact Materials is Not Consistent with FDA's Food Security Preventive Measures Guidance

In January 2002, FDA issued Draft Guidance for food establishments to implement security measures intended to protect the nation's food supply. CFSAN, Draft Guidance: Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance (January 9, 2002). In that guidance, FDA recognized the insignificance of food packaging and other food contact articles in protecting against intentional attacks on the food supply. This Draft Guidance for industry on measures to increase the security of the food supply was directed at conventional food facilities. No mention was made of packaging facilities. In fact, packaging was mentioned merely as one of the items for which the conventional food facility should establish procedures.

FDA announced the issuance of its Final Guidance with a notice in the Federal Register. 68 Fed. Reg. 13931 (March 21, 2003). In the Final Guidance, FDA goes even further in separating "packaging" from "food," mentioning packaging only in the operations section. The Final Guidance suggests that a conventional food establishment develop procedures to ensure that "only known, appropriately licensed or permitted (where applicable) contract manufacturing and packaging operators" be used for food packaging and that food establishments inspect incoming

materials, including packaging. Final Guidance, p. 10. Clearly, FDA has itself demonstrated that packaging and food are two separate things.

The Final Guidance recommends that the food establishment evaluate the incoming packaging for the possibility of any threat to public health. Thus, if the food establishment follows the FDA Final Guidance, any possible threat to the food supply from the packaging or other food contact material will already be identified by the food establishment, well before the material ever contacts food. This Final Guidance demonstrates that there is no need to apply the prior notice requirement to food packaging and other food contact article facilities as FDA proposes in these regulations.

AF&PA submitted comments to FDA on March 6, 2002 endorsing the initial Guidance and its correct distinction between food establishments and food packaging suppliers, their components, and ingredients. At no time in the preparation and commenting on the Guidance did the food industry suggest a change in this distinction, or consider it a need for its implementation of security procedures proposed in the Guidance. If this separation were not considered appropriate by our customers or FDA, the comments of AF&PA would have provoked a rebuttal or clarification that was not made by either.

III. Subjecting Food Packaging and Food Contact Materials to Prior Notice Will Not Further the Purposes of the Bioterrorism Act

The Conference Report on the Bioterrorism Act states that the intent of the bill is "to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public

health emergencies." H. R. Rept. No. 107-481, 107th Cong., 2d Sess., 107 (May 21, 2002). Thus, all the requirements imposed by the Act must be directed at achieving this goal. While many of the provisions of the Bioterrorism Act, when applied to conventional food, will further this purpose, they will not do so if applied to food packaging and other food contact materials. Congress recognized this, and excluded packaging and other food contact articles from the prior notification requirements, and FDA should similarly do so in its regulations.

The potential list of food contact articles is tremendous. For example, if one reviews the broad array of materials FDA regulates in its food additive regulations, 21 C.F.R. Parts 170 through 189, the scope of the substances that FDA considers "food" under the statute becomes clear. These sections do not cover articles typically referred to as "housewares," which are food contact articles such as plates, utensils, and cookware used in the home or retail establishments. These items have traditionally been considered outside the scope of FDA's food additive authority, but are still "food" under the FD&C Act. Because FDA incorrectly attempts to use "food" rather than "article of food" for purpose of triggering the requirements of the proposed regulations, all of these articles, and any of their components, would require prior notification. Thus, all of the following items, and any component of these items, would be subject to prior notification if possibly used with food: paper, paperboard, plastics, most industrial chemicals, metals, glass, pottery and china, rubber products, lubricants, food processing equipment, as well as all utensils.

Applying the prior notice requirement to this broad variety of products will overwhelm both industry and FDA resources, with no benefit as far as increased security for the United States food supply. In fact, due to dilution of resources, this broad approach could have the opposite

effect. It is absurd to believe that a terrorist attack on the food supply will be carried out through packaging. As a technical matter, it would be virtually impossible to insert a poison in packaging with a sustained release mechanism to contaminate food, without the full cooperation of the packaging manufacturer. Packaging manufacturers and food processors have routine procedures in place to ensure that their packaging materials are suitable for use with food. Any possible threat to the food supply from packaging would be uncovered at this stage.

FDA states in the preamble to its proposed regulation that "with respect to articles that can be used for food and non-food uses, FDA believes that prior notice is required if the article is being imported for use as food." 68 Fed. Reg. at 5430. This comment creates an immense burden for the packaging industry, as most food packaging materials and their raw materials are imported in a form other than finished food packaging, and can have many uses in addition to use with food. If food use is only one of the many intended uses of a product upon import, it is clear from FDA's comment that prior notice would be required for all packaging, packaging materials, food contact articles, and all raw materials used to manufacture them, as it is impossible to segregate material that will be used with food from material that will not be used with food within bulk shipments. Because of the significant burden created by imposing the prior notice requirement on these imports, with no commensurate minimization of risk to food safety, food packaging and other food contact materials should not be subject to the prior notice requirements.

IV. Separate Notification for Food Packaging and Food Contact Articles is Duplicative

FDA's proposed regulation requires that the notification contain the complete FDA product code. Proposed 21 C.F.R. 1.288(e)(1)(i). FDA further explains in the preamble that the complete product code includes information about the "container/packaging" of the food. 68 Fed. Reg. at 5436. Consequently, FDA will receive information about the packaging of food through the notification submitted for the food item. Given the express intent of Congress to limit the prior notice requirement to food packaging and other articles in contact with food at the time of import, all information on these materials that FDA is authorized to require will already be presented to FDA through the notification for the food item. It is unclear what purpose requiring a separate notification for the packaging could serve. Such a requirement would be duplicative, and unnecessarily burdensome on both FDA and industry.

As noted above, the technical difficulty involved with carrying out a terrorist attack through packaging is very high. To think a contaminant could survive in packaging or packaging raw materials that do not already contain food through shipment, import, further processing to package food, shipment of the food, the shelf-life of the food, and finally consumption, strains credulity. Congress wisely limited the prior notification requirement to packaging and other articles that already contact food at the time of import, as there is absolutely no risk from material that does not contact food. Further, as FDA proposes to implement the prior notification requirement to include the FDA product code, FDA will receive information about the packaging of all imported food. The purpose of the prior notification is to "enable[e] such article to be inspected at ports of entry into the United States." Bioterrorism Act section 307. If

FDA has a concern about a particular packaging type presenting a risk to food, FDA will already be receiving the information necessary to identify and inspect those articles without requiring a separate notification for the food contact article.

V. FDA Underestimates the Financial Burden of the Proposed Regulation

FDA estimates the cost of the prior notice system using the OASIS codes for food imports (codes 02-52, 54, and 70-72). 68 Fed. Reg. at 5440. Because these categories cover only those items that are traditionally considered "food" under the FD&C Act, this analysis underestimates the impact that FDA's proposed definition of "article of food" will have on imports, and thus the cost of the prior notice proposal. The categories in the OASIS system do not cover the imports of bulk chemicals, polymers, bulk papers, and other precursor materials that are used in food packaging and other food contact articles. Under FDA's proposed regulation, importers of these materials will be required to submit a prior notification if they are aware that the materials may be used with food. Because it is difficult to know for certain every possible use of a bulk chemical, the prudent importer will be forced to submit a notification to ensure that, if the product is to be used with food, it is legal to do so. This creates an unnecessary burden on several levels. For industry, notifications will be required for a vast quantity of material that will not contact food. For FDA, unnecessary resources will be spent processing notifications for materials that may never contact food. FDA should avoid this unnecessary expenditure of resources by following the clearly defined legislative intent and not requiring notification for food contact materials unless, at the time of import, the materials are used in direct contact with food.

In calculating the total cost as stated in the preamble to the proposed regulation, FDA applied improper math. FDA states that there were 4.7 million OASIS import lines that it used to establish its base line cost for this proposal. FDA further states that the average imported entry contained 2.6 lines. "An 'entry line' is an FDA term used by the OASIS reporting system, which refers to a line on an invoice that reflects a certain article specific to manufacturer or packaging: e.g. 100 cases containing 48 six ounce cans of tuna." 68 Fed. Reg. at 5442. FDA then goes on to state that, because there is an average of 2.6 lines per import entry, and there were 4.7 million lines, there were 1,807,692 entries that would require notification. What this ignores is FDA's definition of "article of food" for purposes of this regulation. FDA states that if the manufacturer, or size of the container differs, even though the products are in the same shipment, separate notifications will be required. Thus, under this definition, each "entry line" will require a separate notification. Therefore, although AF&PA considers the appropriate number to be much higher, even assuming the 4.7 million entry lines is correct, the proper number for FDA to use in estimating the cost of this proposal should be the 4.7 million lines. This will increase the cost of the proposal 2.6 times, to $155,193,974. This, in addition to the ignored cost of the notifications for packaging materials and other food contact substances that may be used with food but are not in contact with food at the time of import, demonstrates the excessive burden of this regulation on industry and FDA.

FDA further underestimates the burden of this proposal by not considering the upstream component manufacturers. Because FDA's proposed definition of food would apply to all ingredients of food packaging and other food contact articles, notification must be submitted for the import of all these items. This extends FDA's notification requirement far beyond the

categories FDA considered to include all the inputs used to manufacture these articles. And because these items and the ingredients used to manufacture them are primarily shipped in bulk, with no way to distinguish between the food use from non-food use material, notification will be required for all of it. Thus, the number of notifications required will be much larger than FDA estimates, with an enormous cost to industry and FDA. Also, given that none of these article will be allowed to cross the United States border without proper notification, there will be a tremendous impact on commerce.

FDA's cost estimate also ignores the additional cost that will be imposed on industry with this requirement. Currently, industry has been able to minimize storage costs by taking advantage of "just-in-time" shipping. This means that orders are placed and raw materials arrive just as the factory needs them. This minimizes storage and warehouse costs. Because of the timing requirements of the prior notification, there will be no way to utilize a just-in-time system if it involves a cross-border shipment. There are many instances where a facility may not know by noon of the previous calendar day that it will need a particular input. If this deadline is missed, an additional twenty-four hour wait must be built in, as there is no way to submit a notification for an earlier shipment. This will require facilities to maintain additional inventories to cover for any shortfall in supply that may result.

AF&PA members have adapted to the changing environment since the passage of the North American Free Trade Agreement (NAFTA) and have located facilities on either side of the border. Currently, if one facility requires an input that the other facility has, it is simply shipped over to where it is needed. As this often involves a border crossing, under FDA's proposed

regulation, this practice will no longer be possible. This will once again force the facilities to maintain larger inventories, and will disrupt efficient methods of business. The cost of this disruption is difficult to quantify, as it will require an entirely new model of operation to accommodate the time periods and paperwork burden of the proposed regulation.

Given the extraordinarily high cost of this proposal, FDA should focus its resources where there is the opportunity to benefit the safety of the United States food supply -- conventional food itself. There is no benefit to applying the import notification requirements to food packaging, and doing so amounts to nothing more than a waste of limited resources. FDA has been tasked with an immense obligation, ensuring the safety of the United States food supply, and it must focus its resources on areas where the expenditure of resources will yield returns in increased safety. Prior notice of imports of food packaging and other food contact articles will not achieve this purpose.

The examples of foodborne outbreaks that could be averted by these requirements, to which FDA refers in the preamble, have nothing to do with food packaging. Beginning on page 5454 of the preamble, FDA sets out the cost of five foodborne outbreaks. The "vehicles" for these outbreaks are all conventional foods, and have nothing to do with packaging or other food contact articles. If FDA seriously thinks that food packaging or other food contact articles pose a potential threat from an intentional attack on the food supply, FDA would have estimated the cost of such an attack, and they would have shown that these provisions will minimize that risk, in an attempt to justify the immense burden being placed on the industry. FDA has provided no such cost minimization justification. FDA has simply stated that it feels compelled by the

language of the Bioterrorism Act to implement it in this fashion, even though the cost is immense. While FDA must accurately implement the Bioterrorism Act, this proposed regulation goes too far, and -- in direct violation of the legislative history expressing congressional intent -- imposes a burden without a proper estimate of the benefit or any cost minimization achieved by the proposal. In the absence of such an estimate, FDA's treatment of food packaging and other food contact materials is completely unjustified.

FDA should replace its erroneous definition of "food" with an accurate definition of "article of food" for purposes of the prior notice requirement to exclude food packaging and other food contact articles not in contact with food at the time of import. Doing so is consistent with the statute, the legislative history, and the congressional intent, as well as FDA's mission to protect the safety of the United States food supply under the Bioterrorism Act.

Respectfully submitted,

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